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VIA ELECTRONIC SUBMISSION
Division of Dockets Management (HFA-305) Food and Drug Administration
5630 Fishers Lane Room 1061 Rockville, MD 20852

Docket No. FDA-2011-D-0376 for "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry."

The Organic & Natural Health Association (ONHA) appreciates the opportunity to comment in response to the FDA's revised draft guidance document: "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Revised Draft Guidance for Industry," published in August, 2016.

ONHA is committed to creating a sustainable future by redefining the relationship between corporations and consumers, and ensuring consumers have access to quality products and goods, provided by a supply chain that is committed to transparency and traceability. Our members are raw ingredient suppliers, manufacturers and providers of finished products, the retailers who sell these products, nonprofits who represent quality certification and standards, and consumer organizations.

ONHA's submission is focused on FDA's interest in comments on the following:

- How to compile independent and verifiable data to support FDA's authoritative list;
- Processes that "chemically alter" an ingredient present in the food supply, and
- Manufacturing processes that convert a grandfathered product into an NDI.

How to compile independent and verifiable data to support FDA's authoritative list.

ONHA is highly supportive of the use of NDI notification as a vehicle to ensure dietary supplements are safe, and supports industry initiatives to document the safety profile of ingredients and finished products. However, this Draft Guidance is rooted in a significant design flaw, the assertion that FDA can compile an authoritative list of grandfathered ingredients marketed prior to October 15, 1994. After 22 years of non-enforcement of NDI requirements, the FDA's ability to identify pre-existing (grandfathered) dietary ingredients is severely compromised. Add to that the fact that a preponderance of ingredients in the marketplace today will likely fall short of FDA's proposed requirements relating to NDI. This creates an enormous regulatory burden on an Agency that lacks manpower and resources to manage such a monumental task. Further, the lack of precision regarding what constitutes an NDI, and the number of NDI applications anticipated, threaten to jeopardize the Agency's primary goal: to identify those products and ingredients that could actually pose a safety threat to consumers.

The ability to provide documentation of sales records, advertisements, invoices, etc. is dependent upon record retention of printed documents that are now at least 22 years old. The requirement is archaic and assumes, after the fact, record retention practices that greatly exceed what is required by generally accepted accounting practices, US courts, and the IRS. Even the Sarbanes – Oxley Act, SEC17CFR, section 210.2-06, which requires that work papers and other documents that form the basis of an audit or review, (including financial data and the suggested invoices in the Draft Guidance), be retained for a period of only seven years. In addition, the Draft Guidance precludes affidavits and inclusion in publications such as the 1992 *Herbs of Commerce* as sufficient to support marketing status prior to the defined date.

ONHA understands that the Agency intends to compile an "Authoritative List" of pre-DSHEA (grandfathered) ingredients. It is also clear that although lists developed by industry are deemed insufficient in FDA's view, the Agency will rely on independently verifiable data and information submitted by industry to create its list. It is the ONHA's position that the efficient and effective development of such a list would require that Congress change through statute the effective date of the grandfather provision from October 1994 to the present time.

Short of pursuing Congressional action (a pathway outside the direct scope of the comments requested by the FDA) one readily available alternative is for the FDA to reconsider its position on external expertise and accept all ingredients listed by third parties (trade organization lists, Herbs of Commerce recent editions, etc.) as grandfathered DSHEA ingredients, *unless the FDA is aware of a safety concern*. This approach respects the intent of DSHEA and ensures consumers have immediate and continuing access to all the safe supplements that have entered the market before and after October 1994.

Manufacturing processes that convert a grandfathered product into an NDI

As the Draft Guidance stands, changes in the manufacturing process may change a longstanding grandfathered product into an NDI if the process "alter(s) the physico-chemical structure or properties, purity and impurities, or biological properties (such as bioavailability or toxicity) of the ingredient…" For instance, the utilization of a different part of a plant, or combination of plant parts, requires an NDI. The composition of a pre-DSHEA dietary ingredient in a water solution now formulated as a tincture could change its composition, thus requiring an NDI. The reverse could also be true. Aloe has been used as a dietary ingredient since before October 15, 1994. However, non-deodorized aloe extract has been shown to be potentially carcinogenic; it should therefore not be included on the grandfathered list. It is very unclear how the NDI process, or the process for establishing the authoritative list of grandfathered ingredients, serve to address safety issues.

Manufacturing processes that chemically alter an ingredient in the food supply

Over the past 22 years, there has been significant development in technologies and testing that support enhance purity and bioavailability. With these developments come continual adjustments to standardization rates, in large part responding to consumer demand for higher quality products. The Draft Guidance offers no practical evaluation of what could constitute reasonable standardization. Increasing the standardization for

purity from 20% to 90% requires an NDI, as does extreme alterations in dosage. It is estimated that products undergo reformulation every three years on average, which under the proposed Draft Guideline would require a new NDI submission. This provision will decrease innovation in the industry and reduce consumer access to improved products.

Equally problematic is the Draft Guidance definition of a substance "present in the food supply." If the substance is an NDI (not grandfathered) and is present in the food supply but not chemically altered, then no notification is required. However "present in the food supply" is taken to mean that the article must have been used in conventional food or a conventional food ingredient—not only in a dietary supplement. This definition is too narrow and effectively precludes any ingredient marketed that is a component of the food from which it is derived. Polyphenols marketed as dietary supplements, while derived from berries, would not qualify as "present in the food supply".

The FDA has also taken a position that changing a fermentation medium from one used to make conventional foods in the food supply would likely result in a process it would consider to chemically alter food. The Draft Guidance restricts "not chemically altered" to a process that uses one single raw material manufactured through physical steps only. ONHA suggest that drying, extraction, and distillation solvent extraction (restricted to water, CO2 extraction or organic ethanol) be included in that definition. ONHA asserts that fermentation is a natural and traditional process, (as are Hydrolysis, enzymatic reactions, saponification and kitchen techniques). Placing such highly restrictive boundaries on the fermentation process is inconsistent with current safe food and beverage manufacturing practices.

CONCLUSION

The NDI notification process, with its objective to ensure product safety, was an admirable goal when the Dietary Supplement Health and Education Act passed in 1994. The practicality of instituting a methodology to address a 22-year delay in defining grandfathered ingredients -- using 1994 as a starting date -- is akin to researching scientific studies using microfiche. It is clear that the level of effort required to create, institute and enforce this proposed NDI Draft Guidance would create additional administrative complexity and hamper innovation with no measurable reward.

At the end of the day, the impressive safety record for the dietary supplement industry has been well documented. There is no evidence that the proposed retroactive NDI administrative process will improve dietary supplement safety. It cannot keep pace with product development. And, it fails to further our collective goal to ensure continued product safety for America's consumers.